



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Centers for Medicare & Medicaid Services

[CMS-9074-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—

April through June 2012

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from April through June 2012, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone Number
I CMS Manual Instructions	Ismael Torres	(410) 786-1864
II Regulation Documents Published in the Federal Register	Terri Plumb	(410) 786-4481
III CMS Rulings	Tiffany Lafferty	(410)786-7548
IV Medicare National Coverage Determinations	Wanda Belle	(410) 786-7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI Collections of Information	Mitch Bryman	(410) 786-5258
VII Medicare –Approved Carotid Stent Facilities	Sarah J. McClain	(410) 786-2294
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	JoAnna Baldwin, MS	(410) 786-7205
IX Medicare's Active Coverage-Related Guidance Documents	Lori Ashby	(410) 786-6322
X One-time Notices Regarding National Coverage Provisions	Lori Ashby	(410) 786-6322
XI National Oncologic Positron Emission Tomography Registry Sites	Stuart Caplan, RN, MAS	(410) 786-8564
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	JoAnna Baldwin, MS	(410) 786-7205
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	JoAnna Baldwin, MS	(410) 786-7205
XIV Medicare-Approved Bariatric Surgery Facilities	Kate Tillman, RN, MAS	(410) 786-9252
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	Stuart Caplan, RN, MAS	(410) 786-8564
All Other Information	Annette Brewer	(410) 786-6580

I. Background

Among other things, the Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the

public; and (2) maintaining effective communications with CMS regional offices, State governments, State Medicaid agencies, State survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Revised Format for the Quarterly Issuance Notices

While we are publishing the quarterly notice required by section 1871(c) of the Act, we will no longer republish duplicative information that is available to the public elsewhere. We believe this approach is in alignment with CMS' commitment to the general principles of the President's Executive Order 13563 released January 2011 entitled "Improving Regulation and Regulatory Review," which promotes modifying and streamlining an agency's regulatory program to be more effective in achieving regulatory objectives. Section 6 of Executive Order 13563 requires agencies to identify regulations that may be "outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand or repeal them in accordance with what has been learned." This approach is also in alignment with the President's Open Government and Transparency Initiative that establishes a system of transparency, public participation, and collaboration.

Therefore, this quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS Website or the

appropriate data registries that are used as our resources. This information is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the Website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the Website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and “real time” accessibility. In addition, many of the Websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the Website. These listservs avoid the need to check the Website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a Website proves to be difficult, the contact person listed can provide information.

III. How to Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at <http://www.cms.gov/manuals>.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance, Program No. 93.774, Medicare--Supplementary Medical Insurance Program, and Program No. 93.714, Medical Assistance Program)

Dated: August 8, 2012

Kathleen Cantwell,

Acting Director,

Office of Strategic Operations and

Regulatory Affairs.

BILLING CODE 4120-01-P

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: November 4, 2011 (76 FR 68467), December 16, 2011 (76 FR 78267), February 21, 2012 (77 FR 9931) and May 18, 2012 (77 FR 29648). For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the Website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (April through June 2012)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: <http://cms.gov/manuals>.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400

designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at <http://www.gpo.gov/libraries/>

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most Federal government publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the Medicare Benefit Policy publication titled Allowing Physician Assistants to Perform Skilled Nursing Facility (SNF) Level of Care Certifications and Recertifications use CMS-Pub. 100-02, Transmittal No. 155.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual. For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our Website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number
Medicare General Information (CMS-Pub. 100-01)	
78	October 2012 Quarterly Updates to the CMS Standard File for Reason Codes for the Fiscal Intermediary Shared System (FISS)
Medicare Benefit Policy (CMS-Pub. 100-02)	
155	Allowing Physician Assistants to Perform Skilled Nursing Facility (SNF) Level of Care Certifications and Recertifications
156	Updates to Caps and Limitations on Hospice Payments Caps and Limitations on Hospice Payments Limitation on Payments for Inpatient Care Aggregate Cap on Overall Reimbursement to Medicare-certified Hospices Actual Medicare Payments Counted New Hospices Counting Beneficiaries for Calculation Changing Aggregate Cap Calculation Methods Other Issues

	Updates to the Cap Amount Administrative Appeals
157	July 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS) Outpatient Hospital Services Determining Self-Administration of Drug or Biological
Medicare National Coverage Determination (CMS-Pub. 100-03)	
143	Extracorporeal Photopheresis (ICD-10) Extracorporeal Photopheresis
Medicare Claims Processing (CMS-Pub. 100-04)	
2437	Pharmacy Billing for Drugs Provided "Incident To" a Physician Service This CR rescinds and fully replaces CR 7109.
2438	Revised Editing for Hepatitis B Administration Code G0010 Healthcare Common Procedure Coding System (HCPCS) and Diagnosis Codes
2439	New Waived Tests
2440	July 2012 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
2441	Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits
2442	Claim Adjustment Reason Code (CARC), Remittance Advice Remark Code (RARC), and Medicare Remit Easy Print (MREP) and PC Print Update
2443	Clinical Laboratory Fee Schedule - New Waived Tests
2444	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2445	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2446	New Influenza Virus Vaccine Code Table of Preventive and Screening Services Healthcare Common Procedure Coding System (HCPCS) and Diagnosis Codes CWF Edits on FI/AB MAC Claims CWF Edits on Carrier/AB MAC Claims CWF A/B Crossover Edits for FI/AB MAC and Carrier/AB MAC Claims
2447	Additional Fields Added to the Outlier Reconciliation Lump Sum Utility Procedure for Medicare Contractors to Perform and Record Outlier Reconciliation Adjustments
2448	Medicare System Update to Include Claim Level Referring Physician Data and Insuring Hospice Certifying Physician Identifiers Are Fully Processed Completing the Uniform (Institutional Provider) Bill (Form CMS 1450) for Hospice Election Data Required on the Institutional Claim to Medicare Contractor
2449	Modification to CWF, FISS, MCS and VMS to Return Submitted Information when there Is a CWF Name and HIC Number Mismatch. Disposition Code 55 (Personal Characteristic Mismatch)
2450	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2012 Update
2451	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2452	Critical Access Hospital (CAH) Physician Rendering Anesthesia in a Hospital

	Outpatient Setting
2453	CY 2012 OPPTS Payment Adjustment for Certain Cancer Hospitals Payment Adjustment for Certain Cancer Hospitals Payment Adjustment for Certain Cancer Hospitals for CY 2012 Transitional Outpatient Payments (TOPs) for CY 2010 through February 29, 2012
2454	Contractor and Common Working File (CWF) Additional Instructions Related to Change Request (CR) 7633 - Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse Claim Adjustment Reason Codes, Remittance Advice Remark Codes, Group Codes, and Medicare Summary Notice Messages Additional CWF and Contractor Requirements
2455	Hospital Dialysis Services for Patients with and without End Stage Renal Disease (ESRD)
2456	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2457	Revisions of the Financial Limitation for Outpatient Therapy Services – Section 3005 of the Middle Class Tax Relief and Job Creation Act of 2012 Application of Financial Limitations Claims Processing Requirements for Financial Limitations Notification for Beneficiaries Exceeding Financial Limitations
2458	Systematic Validation of Payment Group Codes for Prospective Payment Systems (PPS) Based on Patient Assessments Systematic Validation of Claims Information Using Patient Assessments
2459	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2460	Issued to a specific audience, not posted to Internet/Intranet/ due to Confidentiality of Instruction
2461	Automated Tracking and Reporting of Recovery Audit-Associated Reopenings and Appeals
2462	New Physician Specialty Code for Sleep Medicine and Sports Medicine Physician Specialty Codes
2463	New Fiscal Intermediary Shared System (FISS) Edit to Review Medicare Outpatient Prospective Payment System (OPPS) Payments Exceeding Charges. Verification Edit for Claims with OPPS Payments
2464	Enhance the Multi-Carrier System (MCS) and ViPS Medicare System (VMS) to maintain five full years of pricing data and to automatically price claims/adjustments at the rates in effect at the dates of service. Update Factor for Fee Schedule Services Online Pricing Files for DMEPOS
2465	Assigned Codes for Home Oxygen Use for Cluster Headache (CH) in a Clinical Trial (ICD-10) Oxygen and Oxygen Equipment
2466	Calendar Year 2013 and After Payments to Home Health Agencies That Do Not Submit Required Quality Data
2467	July Quarterly Update for 2012 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule
2468	July 2012 Integrated Outpatient Code Editor (I/OCE) Specifications Version 13.2

2469	Instructions for Downloading the Medicare ZIP Code File for October 2012
2470	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) - October 2012
2471	Common Edits and Enhancements Modules (CEM) Code Set Update
2472	Coding Changes to Ultrasound Diagnostic Procedures for Transesophageal Doppler Monitoring Transeophageal Doppler Used for Cardiac Monitoring Coding Requirements for Transesophageal Doppler Used for Cardiac Monitoring Furnished Before October 1, 2012 Coding Requirements for Transesophageal Doppler Used for Cardiac Monitoring Furnished On or After October 1, 2012 Correct Place of Service (POS) Code for Transesophageal Doppler Used for Cardiac Monitoring Services on Professional Claims
2473	Extracorporeal Photophoresis (ICD-10) Billing Requirements for Extracorporeal Photophoresis Healthcare Common Procedural Coding System (HCPCS), Applicable Diagnosis Codes and Procedure Code Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RAs) and Claim Adjustment Reason Code
2474	Handling Misdirected Claims for Part B Items and Services Disposition of Misdirected Claims to the B/MAC/Carrier/DME MAC A Local B/MAC/Carrier Receives a Claims for Services that are in Another Local B/MAC/Carrier's Payment Jurisdiction A Local B/MAC/Carrier Receives a Claim for Services that are in A DME MAC's Payment Jurisdiction A DME MAC Receives a Claim for Services that are in A Local B/MAC/Carrier's Payment Jurisdiction A Local B/MAC/Carrier/DME/MAC Receives a Claim for an RRB Beneficiary A Local B/MAC/Carrier/DME/MAC Receives a Claim for a UMWA Beneficiary Medicare Carrier or RRB-Named Carrier to Welfare Carrier Protests Concerning Transfer of Requests for Payment to Carrier Transfer of Claims Material Between Carrier and Intermediary (FI) A DME MAC receives a Paper Claim with Items or Services that are in Another DME MAC's Payment Jurisdiction Handling Incomplete or Invalid Claims
2475	Internet Only Manual (IOM) Update for Laboratory Services and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Claims Processed under the End Stage Renal Disease Prospective Payment System (ESRD PPS Carrier Jurisdiction of Requests for Payments Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies, Parental and Enteral Nutrition (PEN) Mandatory Assignment on Carrier Claims Mandatory Assignment and Other Requirements for Home Dialysis Supplies and Equipment Paid Under Method II on Claims Submitted to Carriers Method of Payment for Clinical Laboratory Tests - Place of Service Variation Billing for End Stage Renal Disease (ESRD) Related Laboratory Tests

	Automated Multi-Channel Chemistry (AMCC) Tests for ESRD Beneficiaries Automated Multi-Channel Chemistry (AMCC) Tests for ESRD Beneficiaries Pricing Modifiers Payment for Home Dialysis Supplies and Equipment DMERC, Carrier and FI Determination of ESRD Method Selection Installation and Delivery Charges for ESRD Equipment Elimination of Method II Home Dialysis
2476	Screening for Sexually Transmitted Infections (STIs) and High Intensity Behavioral Counseling (HIBC) to Prevent STIs (ICD-10) Screening for Sexually Transmitted Infections (STIs) and High Intensity Behavioral Counseling (HIBC) to Prevent STIs Healthcare Common Procedure Coding System (HCPCS) Codes for Screening for STIs and HIBC to Prevent STIs Diagnosis Code Reporting Billing Requirements Specialty Codes and Place of Service (POS)
2477	Revision of Medicare Summary Notice (MSN) for Non-Competitive Bid Claims Modifying the Timely Filing Exceptions on Retroactive Medicare Entitlement and Retroactive Medicare Entitlement Involving State Medicaid Agencies Exceptions Allowing Extension of Time Limit Retroactive Medicare Entitlement Retroactive Medicare Entitlement Involving State Medicaid Agencies
2478	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
2479	July 2012 Update of the Ambulatory Surgical Center Payment System (ASC)
2480	Advanced Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131, Updated Manual Instructions Introduction - General Information General Statutory Authority - Financial Liability Protections Provisions (FLP) of Title XVII Applicability to Limitation On Liability (LOL) Compliance with Limitation on Liability Provisions ABN Scope Voluntary Uses Issuers of ABNs (Notifiers) Recipients of the ABN Representatives of Beneficiaries ABN Triggering Events Proper Notice Documents General Notice Preparation Requirements Completing the ABN Retention Requirements Effective Delivery Options for Delivery Other than in Person Effects of Lack of Notification, Medicare Review and Claim Adjudication ABN Standards for Upgraded Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) ABNs for Denials Under Sec. 1834(a)(17)(B) of the Act (Prohibition Against Unsolicited Telephone Contacts)

	<p>ABNs for Claims Denied Under Sec. 1834(j)(1) of the Act (Supplier Did Not Meet Supplier Number Requirements)</p> <p>ABNs for Claims Denied in Advance Under Sec. 1834(a)(15) of the Act (When a Request for an Advance Determination of Coverage is Mandatory)</p> <p>Situations In Which Advance Coverage Determinations Are Mandatory</p> <p>ABNs for items listed in a DMEPOS Competitive Bidding Program</p> <p>Collection of Funds and Refunds</p> <p>Physicians' Services Refund Requirements</p> <p>DMEPOS Refund Requirements (RR) Provision for Claims for Medical Equipment and Supplies</p> <p>Time Limits and Penalties for Physicians and Suppliers in Making Refunds</p> <p>Supplier's Right to Recover Resalable Items for Which Refund Has Been Made</p> <p>CMS Regional Office (RO) Referral Procedures</p> <p>Special Considerations</p> <p>Obligation to Bill Medicare</p> <p>Emergencies or Urgent Situations/ Ambulance Transport Hospice and Comprehensive Outpatient Rehabilitation Facility (CORF)</p> <p>Special Issues Associated with the Advance Beneficiary Notice (ABN) for Hospice Providers</p> <p>Special Issues Associated with the Advance Beneficiary Notice (ABN) for CORFS</p>
2481	July Update to the CY 2012 Medicare Physician Fee Schedule Database (MPFSDB)
2482	Updates to Caps and Limitations on Hospice Payments
2483	July 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS) Payment Window for Outpatient Services Treated as Inpatient Services Inpatient-only Services
2484	October Quarterly Update to 2012 Annual Update of Healthcare Common Procedure Coding System (HCPCS) Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement
2485	Medicare Contractor Annual Update of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)
2486	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
2487	<p>Internet Only Manual (IOM) Update for Laboratory Services and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Claims Processed under the End Stage Renal Disease Prospective Payment System (ESRD PPS)</p> <p>Carrier Jurisdiction of Requests for Payments</p> <p>Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies, Parental and Enteral Nutrition (PEN)</p> <p>Mandatory Assignment on Carrier Claims</p> <p>Mandatory Assignment and Other Requirements for Home Dialysis Supplies and Equipment Paid Under Method II on Claims Submitted to Carriers</p> <p>Method of Payment for Clinical Laboratory Tests - Place of Service Variation</p> <p>Billing for End Stage Renal Disease (ESRD) Related Laboratory Tests</p> <p>Automated Multi-Channel Chemistry (AMCC) Tests for ESRD Beneficiaries</p>

	<p>Specimen Drawing for Dialysis Patients Pricing Modifiers</p> <p>Payment for Home Dialysis Supplies and Equipment</p> <p>DMERC, Carrier and FI Determination of ESRD Method Selection</p> <p>Installation and Delivery Charges for ESRD Equipment</p> <p>Elimination of Method II Home Dialysis</p>
2488	None
2489	None
2490	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
2491	None
2492	None
2493	Issued to a specific, audience not posted to Internet/Intranet due to Confidentiality of Instruction
Medicare Secondary Payer (CMS-Pub. 100-05)	
84	<p>ECRS Web User Guide Version 4.4</p> <p>ECRS Web Quick Reference Card Version 5.2.1</p>
85	<p>Validation of Recovery Audit Program New Issues</p> <p>Validation of Recovery Audit Program New Issues</p>
86	Clarifications of Medicare Conditional Payment Policy and Billing Procedures for Liability, No-Fault and Workers - Compensation Medicare Secondary Payer (MSP) Claims
Medicare Financial Management (CMS-Pub. 100-06)	
208	Overpayment Recovery from Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
209	<p>New Physician Specialty Code for Sleep Medicine and Sports Medicine</p> <p>Part D(1) - Claims Processing Timeliness - All Claims</p> <p>Part E - Interest Payment Data</p> <p>Classification of Claims for Accounting</p> <p>Physician/Limited License Physician Specialty Codes</p> <p>Non-Physician Practitioner/Supplier Specialty Codes Exhibit</p> <p>Definitions of Provider Specialty Codes for Opt Out Reporting Exhibit</p>
210	Validation of Recovery Audit Program New Issues
Medicare State Operations Manual (CMS-Pub. 100-07)	
00	None
Medicare Program Integrity (CMS-Pub. 100-08)	
413	Issued to a specific audience not posted to Internet/Intranet due to Confidentiality of Instruction
414	<p>General Update to Chapter 15 of the Program Integrity Manual (PIM) – Part IV</p> <p>NPI-Legacy Combinations</p> <p>Community Mental Health Centers (CMHCs)</p> <p>Comprehensive Outpatient Rehabilitation Facilities (CORFs)</p> <p>Hospices</p> <p>CLIA Labs</p> <p>Pharmacies</p> <p>Portable X-Ray Suppliers (PXRSS)</p> <p>Radiation Therapy Centers</p> <p>Intensive Cardiac Rehabilitation (ICR)</p> <p>Medicare Advantage and Other Managed Care Organizations</p>

	Individual Practitioners Anesthesiology Assistants Audiologists Certified Nurse-Midwives Certified Registered Nurse Anesthetists (CRNAs) Clinical Nurse Specialists Clinical Psychologists Nurse Practitioners Occupational and Physical Therapists in Private Practice Physicians Physician Assistants (PAs) Psychologists Practicing Independently Registered Dietitians Speech Language Pathologists in Private Practice Manufacturers of Replacement Parts/Supplies for Prosthetic Implants or Implantable Durable Medical Equipment (DME) Surgically Inserted at an ASC Diabetes Self-Management Training (DSMT) Mass Immunizers Who Roster Bill Medicaid State Agencies Suppliers Not Eligible to Participate Basic Information (Section 1 of the Form CMS-855) Correspondence Address Section 2 of the Form CMS-855A Section 2 of the Form CMS-855A Supervising Physicians Desk and Site Reviews Background Scope of Site Visit Changes of Information and Ownership Movement of Providers and Suppliers into the High Level Reactivations
415	General Update to Chapter 15 of the Program Integrity Manual (PIM) - Part V Application Returns, Rejections and Denials Returns Rejections Denials for Incomplete Applications
416	General Update to Chapter 15 of the Program Integrity Manual (PIM) - Part III
417	Issued to a specific audience not posted to Internet/Intranet due to Confidentiality of Instruction
418	OMB Collection Number
419	Issued to a specific audience not posted to Internet/Intranet due to Confidentiality of Instruction
420	Issued to a specific audience not posted to Internet/Intranet due to Confidentiality of Instruction
421	General Update to Chapter 15 of the Program Integrity Manual (PIM) - Part VI
422	Independent Diagnostic Testing Facility (IDTF) Standards Multi-State Independent Diagnostic Testing Facilities (IDTFs) Interpreting Physicians Technicians

	Special Procedures and Supplier Types Non-Certified Suppliers and Individual Practitioners Approval of Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Changes of Information - General Procedures Changes of Information and Complete Form CMS-855 Applications Incomplete or Unverifiable Changes of Information Special Change Request Instructions Regarding Certified Providers, Ambulatory Surgical Centers, and Portable X-ray Suppliers Voluntary Terminations Non-Form CMS-855 Enrollment Activities Contractor Communications Provider-Based Form CMS-855B Applications Submitted by Hospitals Participation (Par) Agreements and the Acceptance of Assignment Assignment of Part B Provider Transaction Access Numbers (PTANs) Establishing an Effective Date of Medicare Billing Privileges Reserved for Future Use On-site Inspections and Site Verifications Site Verifications Reserved for Future Use National Supplier Clearinghouse (NSC) Model Letters for Claims against Surety Bonds Zone Program Integrity Contractor (ZPIC) Identified Revocations CMS Satellite Office or Regional Office Identified Revocations
423	General Update to Chapter 15 of the Program Integrity Manual (PIM) - Part VII
424	General Update to Chapter 15 of the Program Integrity Manual (PIM) - Part VI
425	Provider Self Audits
426	Process for Handling Electronic Submission of Medical Documentation (esMD) Time Frames for Submission
Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)	
00	None
Medicare Quality Improvement Organization (CMS-Pub. 100-10)	
17	QIO Manual Chapter 5 – “Quality of Care Review” Introduction to Quality of Care Reviews Organization of Chapter Authority for Conducting Quality of Care Reviews Definitions Related to Quality of Care Reviews Beneficiary Complaint (Oral or Written) Review Eligibility for Beneficiary Complaint Review Beneficiary Complaint Intake Stage Scope of Complaint Initial Information Collection Initial Offer of Review Use of CMS-Designated Case Review System Immediate Advocacy Objectives of Immediate Advocacy

	<p>Eligibility for Immediate Advocacy Practitioner/Provider Consent to Participate in Immediate Advocacy</p> <p>Immediate Advocacy Procedures</p> <p>Discontinuation of Immediate Advocacy</p> <p>Retrospective Beneficiary Complaint Review</p> <p>Retrospective Beneficiary Complaint: Preparation and Forwarding of Complaint Form</p> <p>Retrospective Beneficiary Complaint: Follow-up Regarding Return of Signed Complaint Form</p> <p>Retrospective Beneficiary Complaint: Complaints Not Submitted in Writing (i.e., Oral Complaints)</p> <p>Retrospective Beneficiary Complaint: Receipt of a Signed Beneficiary Complaint</p> <p>Retrospective Beneficiary Complaint: Preparation of Beneficiary Complaint Folder</p> <p>Retrospective Beneficiary Complaint: Forwarding of Complaint to Review Analyst</p> <p>Retrospective Beneficiary Complaint: Requesting Medical Information</p> <p>Retrospective Beneficiary Complaint: Issuing a Claim Denial</p> <p>Retrospective Beneficiary Complaint: Review and Preparation of Medical Information</p> <p>Retrospective Beneficiary Complaint: Quality of Care Review Stage</p> <p>Retrospective Beneficiary Complaint: New Concerns Raised by the Beneficiary</p> <p>Retrospective Beneficiary Complaint: Preparation of Quality Review Decision (QRD) Form</p> <p>Retrospective Beneficiary Complaint: Receipt and Review by the Initial Determination Peer Reviewer (IDPR)</p> <p>Retrospective Beneficiary Complaint: Return and Review of Interim Initial Determination</p> <p>Retrospective Beneficiary Complaint: Opportunity for Discussion Stage</p> <p>Retrospective Beneficiary Complaint: Notification of Opportunity for Discussion</p> <p>Retrospective Beneficiary Complaint: Oral or Written Response to Opportunity for Discussion</p> <p>Retrospective Beneficiary Complaint: Prohibition on Submission of New/Additional Medical Information</p> <p>Retrospective Beneficiary Complaint: Review of Information Submitted During Opportunity for Discussion Stage</p> <p>Retrospective Beneficiary Complaint: No Response to Opportunity for Discussion</p> <p>Retrospective Beneficiary Complaint: Preparation of Final Initial Determination Letter to Practitioners/Providers with Request to Disclose</p> <p>Retrospective Beneficiary Complaint: Failure to Respond to the Final Initial Determination and Right to Re-Review</p> <p>Retrospective Beneficiary Complaint: Responsibility to Protect Information and Destruction of Materials</p> <p>Retrospective Beneficiary Complaint: Re-Review Stage</p> <p>Retrospective Beneficiary Complaint: Re-Review Peer Reviewer</p> <p>Retrospective Beneficiary Complaint: Preparation of Re-Review Disclosure</p>
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	<p>Package</p> <p>Retrospective Beneficiary Complaint: QIO's Final Decision, Preparing and Mailing Letter to Beneficiary</p> <p>Retrospective Beneficiary Complaint: Procedures for Closing a Complaint</p> <p>Review Concurrent Beneficiary Complaint Review</p> <p>Concurrent Beneficiary Complaint: Preparation and Forwarding of Standard Complaint Form</p> <p>Concurrent Beneficiary Complaint: Follow-up Regarding Return of Signed Complaint Form</p> <p>Concurrent Beneficiary Complaint: Complaints Not Submitted in Writing (i.e., Oral Complaints)</p> <p>Concurrent Beneficiary Complaint: Receipt of a Signed Beneficiary Complaint</p> <p>Concurrent Beneficiary Complaint: Preparation of Beneficiary Complaint Folder</p> <p>Concurrent Beneficiary Complaint: Forwarding of Complaint to Review Analyst</p> <p>Concurrent Beneficiary Complaint: Requesting Medical Information</p> <p>Concurrent Beneficiary Complaint: Issuing a Claim Denial</p> <p>Concurrent Beneficiary Complaint: Review and Preparation of Medical Information</p> <p>Concurrent Beneficiary Complaint: Quality of Care Review Stage</p> <p>Concurrent Beneficiary Complaint: New Concerns Raised by the Beneficiary</p> <p>Concurrent Beneficiary Complaint: Preparation of Quality Review Decision (QRD) Form</p> <p>Concurrent Beneficiary Complaint: Return and Review of Interim Initial Determination</p> <p>Concurrent Beneficiary Complaint: Opportunity for Discussion Stage</p> <p>Concurrent Beneficiary Complaint: Notification of Opportunity for Discussion</p> <p>Concurrent Beneficiary Complaint: Oral or Written Response to Opportunity for Discussion</p> <p>Concurrent Beneficiary Complaint: Prohibition on Submission of New/Additional Medical Information</p> <p>Concurrent Beneficiary Complaint: Prohibition on Submission of New/Additional Medical Information</p> <p>Concurrent Beneficiary Complaint: No Response to Opportunity for Discussion</p> <p>Concurrent Beneficiary Complaint: Preparation of Final Initial Determination Letter to Practitioners/Providers with Request to Disclose</p> <p>Concurrent Beneficiary Complaint: Failure to Respond to the Final Initial Determination and Right to Re-Review</p> <p>Concurrent Beneficiary Complaint: Responsibility to Protect Information and Destruction of Materials</p> <p>Concurrent Beneficiary Complaint: Re-Review Stage</p> <p>Concurrent Beneficiary Complaint: Re-Review Peer Reviewer</p> <p>Concurrent Beneficiary Complaint: Preparation of Re-Review Disclosure Package</p> <p>Concurrent Beneficiary Complaint: QIO's Final Decision, Preparing and</p>
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	<p>Mailing Letter to Beneficiary</p> <p>Concurrent Beneficiary Complaint: Procedures for Closing a Beneficiary Complaint Review</p> <p>Direct Advocacy</p> <p>Objectives of Direct Advocacy</p> <p>Practitioner/Provider Consent to Participate in Direct Advocacy</p> <p>Direct Advocacy Procedures</p> <p>Discontinuation of Direct Advocacy</p> <p>General Quality of Care Reviews</p> <p>Concerns Identified During Other Review Activities</p> <p>Referrals</p> <p>Referrals from Other Federal Government Organizations</p> <p>Overlap of Review Authority</p> <p>Tracking and Trending of Data</p> <p>Retrospective General Quality of Care Review</p> <p>Retrospective General Quality Review: Preparation of General Quality of Care Review Folder</p> <p>Retrospective General Quality Review: Review of Folder by Review Analyst</p> <p>Retrospective General Quality Review: Requesting Medical Information</p> <p>Retrospective General Quality Review: Issuing a Claim Denial</p> <p>Retrospective General Quality Review: Review and Preparation of Medical Information</p> <p>Retrospective General Quality Review: Quality of Care Review Stage</p> <p>Retrospective General Quality Review: Preparation of Quality Review Decision (QRD) Form</p> <p>Retrospective General Quality Review: Receipt and Review by the Initial Determination Peer Reviewer (IDPR)</p> <p>Retrospective General Quality Review: Return of Interim Initial Determination</p> <p>Retrospective General Quality Review: Return of Interim Initial Determination</p> <p>Retrospective General Quality Review: Submission of Oral or Written Response to Opportunity for Discussion</p> <p>Retrospective General Quality Review: Prohibition on Submission of New/Additional Medical Information</p> <p>Retrospective General Quality Review: Review of Information Submitted during Opportunity for Discussion Stage</p> <p>Retrospective General Quality Review: No Response Received to Opportunity for Discussion</p> <p>Retrospective General Quality Review: Preparation of Final Determination Letter</p> <p>Retrospective General Quality Review: Failure to Respond to the Final Initial Determination and Right to Re-Review</p> <p>Retrospective General Quality Review: Responsibility to Protect Information and Destruction of Materials</p> <p>Retrospective General Quality Review: Re-Review Stage</p> <p>Retrospective General Quality Review: Re-Review Peer Reviewer</p> <p>Retrospective General Quality Review: Preparation of Re-Review Package</p> <p>Retrospective General Quality Review: Preparation and Mailing of Final Re-</p>
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	<p>Review Determination Letter</p> <p>Retrospective General Quality Review: Procedures for Closing Review</p> <p>Concurrent General Quality of Care Review</p> <p>Concurrent General Quality Review: Preparation of General Quality of Care Review Folder</p> <p>Concurrent General Quality Review: Review of Folder by Review Analyst</p> <p>Concurrent General Quality Review: Requesting Medical Information</p> <p>Concurrent General Quality Review: Issuing a Claim Denial</p> <p>Concurrent General Quality Review: Review and Preparation of Medical Information</p> <p>Concurrent General Quality Review: Quality of Care Review Stage</p> <p>Concurrent General Quality Review: Preparation of Quality Review Decision (QRD) Form</p> <p>Concurrent General Quality Review: Receipt and Review by the Initial Determination Peer Reviewer (IDPR)</p> <p>Concurrent General Quality Review: Return and Review of Interim Initial Determination</p> <p>Concurrent General Quality Review: Opportunity for Discussion Stage</p> <p>Concurrent General Quality Review: Notification of Opportunity for Discussion</p> <p>Concurrent General Quality Review: Submission of Oral or Written Response to Opportunity for Discussion</p> <p>Concurrent General Quality Review: Prohibition on Submission of New/Additional Medical Information</p> <p>Concurrent General Quality Review: Review of Information Submitted During Opportunity for Discussion Stage</p> <p>Concurrent General Quality Review: No Response Received to Opportunity for Discussion</p> <p>Concurrent General Quality Review: Preparation of Final Determination Letter</p> <p>Concurrent General Quality Review: Failure to Respond to the Final Initial Determination and Right to Re-Review</p> <p>Concurrent General Quality Review: Destruction of Materials Associated with the Review</p> <p>Concurrent General Quality Review: Re-Review Stage</p> <p>Concurrent General Quality Review: Re-Review Peer Reviewer</p> <p>Concurrent General Quality Review: Preparation of Re-Review Package</p> <p>Concurrent General Quality Review: Preparation and Mailing of Final Review Determination Letter to the Practitioner or Provider</p> <p>Concurrent General Quality Review: Preparation and Mailing of Final Re-Review Determination Letter to the Practitioner or Provider</p> <p>Concurrent General Quality Review: Procedures for Closing a General Quality of Care Review</p> <p>Quality Improvement Initiatives</p> <p>Unwillingness to Cooperate</p> <p>Development of a Quality Improvement Initiative</p> <p>Time Frames for Development of a Quality Improvement Initiative</p> <p>Quality Improvement Initiative Not Needed</p> <p>Quality Improvement Initiative Root Cause Analysis</p> <p>“Stand-Alone” or Isolated Concerns</p>
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	Intervention and Improvement Plan Monitoring Quality Improvement Initiatives Reporting Results of System-Wide Change Quality Improvement Initiatives Medicare Quality of Care Complaint Form Quality Review Decision (QRD) Form Interim Initial Determination Letter for Practitioners and Providers Final Initial Determination Letter to Practitioners/Providers with Request to Disclose (For Beneficiary Complaints) Re-Review Determination Letter to Providers/Practitioners with Request to Disclose (For Beneficiary Complaints) Letter to Beneficiary – QIO’s Final Decision Final Determination Letter (General Quality of Care Reviews) Re-Review Determination Letter to the Provider or Practitioner (General Quality of Care Reviews) Retrospective Beneficiary Complaint Review Time Frames Concurrent Beneficiary Complaint Review Time Frames Retrospective General Quality of Care Review Time Frames Concurrent General Quality of Care Review Time Frames
Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)	
00	None
Medicare Managed Care (CMS-Pub. 100-16)	
105	Chapter 13: Medicare Managed Care Beneficiary Grievances, Organization Determinations, and Appeals Applicable to Medicare Advantage Plans, Cost Plans, and Health Care Prepayment Plans (HCPPs), (collectively referred to as Medicare Health Plans) Medicare Managed Care Beneficiary Grievances, Organization Determinations, and Appeals Definition of Terms Responsibilities of the Medicare Health Plan Grievances Appeals Representatives Representatives Filing on Behalf of Enrollees Authority of a Representative Notice Delivery to Representatives Complaints That Contain Elements of Both Appeals and Grievances Distinguishing Between Appeals and Grievances Procedures for Handling a Grievance Procedures for Handling Misclassified Grievances Written Explanation of Grievance Procedures Organization Determinations Special Jurisdictional Rules for Claims Processing and Appeals for Medicare Cost Plans and HCPPs Standard Time Frames for Organization Determinations Who Must review an Organization Determination Written Notification of Medicare Health Plan Decision Examples of Unacceptable/Acceptable Denial Rationale Notice Requirements for Non-contract Providers How the Medicare Health Plan Processes Requests for Expedited

Organization Determinations Defining the Medical Exigency Standard Action Following Denial of Request for Expedited Review Action Following Acceptance of Requests for Expedited Determinations Notice Requirements for Expedited Organization Determinations Effect of Failure to Provide Timely Notice Parties to the Organization Determination for Purposes of an Appeal Non-Contract Provider Appeals Who May Request Reconsideration Medicare Health Plan Procedures for Accepting Standard Pre-service Reconsiderations from Physicians How to Request a Standard Reconsideration Conditions Upon Which a Plan May Grant a Good Cause for Late Filing Exception Withdrawal of Request for Reconsideration Who Must Reconsider an Adverse Organization Determination Standard Reconsideration of a Pre-Service Request Adverse Plan Reconsideration Determination Standard Reconsideration of a Request for Payment How the Medicare Health Plan Processes Requests for Expedited Reconsiderations Preparing the Case File for the Independent Review Entity Storage of Appeal Case Files by the Independent Review Entity QIO Fast-Track Appeals of Coverage Terminations in Certain Provider Settings (SNF, HHA, and CORF) Notice of Medicare Non-Coverage (NOMNC) Meaning of Valid Delivery When to Issue the Notice of Medicare Non-Coverage (NOMNC) Detailed Explanation of Non-Coverage (DENC) When to Issue the Detailed Explanation of Non-Coverage Enrollee Procedures to Request Fast-Track Review of Provider Service Terminations Effect of a QIO Fast-Track Determination Fast-Track Reconsiderations for Medicare Health Plan Enrollees The Role of the Enrollee and Liability The Responsibilities of the QIO If the QIO Reaffirms its Decision If the QIO’s Decision is Reversed Handling Misdirected Records QIO Authority to Request Enrollee Records Determination of Amount in Controversy Medicare Appeals Council (MAC) Review Filing a Request for Medicare Appeals Council (MAC) Review Time Limit for Filing a Request for Medicare Appeals Council (MAC) Review Medicare Appeals Council (MAC) Review Procedures MAC Review Procedures Judicial Review Requesting Judicial Review Reopening and Revising Determinations and Decisions

	<p>Independent Review Entity Monitoring of Effectuation Requirements</p> <p>Effectuation Requirements When an Individual Has Disenrolled from a Medicare Health Plan</p> <p>Effectuation Requirements When a Medicare Health Plan Contract Ends</p> <p>Immediate Review Process for Hospital Inpatients in Medicare Health Plans</p> <p>Scope of the Instructions</p> <p>Special Considerations</p> <p>Notifying Enrollees of their Right to an Immediate Review</p> <p>Delivery of the Important Message from Medicare</p> <p>The Follow-Up Copy of the Signed Important Message from Medicare Rules and Responsibilities When an Enrollee Requests an Immediate Review</p> <p>The Role of the Enrollee and Liability</p> <p>The Responsibilities of the Medicare Health Plan</p> <p>The Role of the QIOs</p> <p>Effect of a QIO Immediate Review Determination</p> <p>General Notice Requirements</p> <p>Number of Copies</p> <p>Reproduction</p> <p>Length and Page Size</p> <p>Contrast of Paper and Print</p> <p>Modifications</p> <p>Font</p> <p>Customization</p> <p>Retention of the Notices</p> <p>Completing the Notices</p> <p>Translated Notices</p> <p>Hospital Requested Review</p> <p>Effect of the Hospital Requested Determination</p> <p>Immediate Reconsiderations for Hospital Inpatients in Medicare Health Plans</p> <p>Liability for Hospital Costs</p> <p>The Role of the Enrollee and Liability</p> <p>The Responsibilities of the QIO</p> <p>If the QIO Reaffirms its Decision</p> <p>If the QIO's Decision is Reversed</p> <p>Data</p> <p>Notice of Denial of Medical Coverage and Notice of Denial of Payment</p> <p>Beneficiary Appeals and Quality of Care Grievances Explanatory Data Report</p> <p>An Important Message from Medicare About Your Rights</p> <p>Detailed Notice of Discharge</p> <p>Appointment of Representative - Form CMS-1696</p> <p>Model Notice of Right to an Expedited Grievance</p> <p>Waiver of Liability Statement</p> <p>Notice of Medicare Non-Coverage (NOMNC)</p> <p>Detailed Explanation of Non-Coverage (DENC)</p> <p>Model Notice of Appeal Status</p>
Medicare Business Partners Systems Security (CMS-Pub. 100-17)	
00	None

Demonstrations (CMS-Pub. 100-19)	
00	None
One Time Notification (CMS-Pub. 100-20)	
1060	Implementation of the Award for the Jurisdiction H Part A and Part B Medicare Administrative Contractor (JH A/B MAC) Including New Workload Numbers for Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, and Texas as well as for the J4 WPS Legacy Part A Workload
1061	Implementation of the Award for the Jurisdiction 8 Part A and Part B Medicare Administrative Contractor (J8 A/B MAC) including New Workload Numbers for Indiana and Michigan
1062	Health Insurance Portability and Accountability Act (HIPAA) 5010 and D.0 Annual Re-Certification Program
1063	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1064	Health Insurance Portability and Accountability Act (HIPAA) 5010 837 Institutional (837I) Edits and 5010 837 Professional (837P) Edits – October 2012
1065	Addition of New Common Working File (CWF) Medicare Secondary Payer (MSP) Utilization Edit Codes for CWF to Send the Shared Systems When the Diagnosis Code on the Claim Is Considered a Match with the Family of DX Codes in CWF for Non-Group Health Plan (NGHP) MSP Claims
1066	Implementation of the HIPAA Version 5010 276/277 Claim Status Edits October 2012 Release
1067	Fee for Service Common Eligibility Services Conference Calls and Research
1068	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1069	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1070	Request to Require Hours for Research and Conference Calls with Maintainers, MACs, and EDCs and Additional Requirements for IDR Shared Systems
1071	Expansion of the Laboratory National Coverage Determination (NCD) Edit Software
1072	Fiscal Intermediary Shared System (FISS) System Enhancement for Including Line Level Rendering Physicians/Practitioners National Provider Identifier (NPI) and Name Information in the Comprehensive Error Rate Testing (CERT) Resolution Record
1073	American Recovery and Reinvestment Act of 2009 Electronic Health Record (EHR) Incentive Program: Financial Information File Transfer Modifications for Eligible Hospitals
1074	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1075	Medicare Fee-for-Service (FFS) Editing and Flat File Utility
1076	Health Insurance Portability and Accountability (HIPAA) 5010/D.0 Fixes - October 2012
1077	Update to the Fiscal Intermediary Shared Systems (FISS) Outpatient Provider Specific File (OPSF) for Children's Hospitals
1078	

1079	New Occurrence Code to Report Date of Death
1080	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1081	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1082	FISS update for Clinical Laboratory Fee Schedule upload to include Kansas Payment Locality Structure
1083	Temporary Direction to Accommodate Organ Donor Complications Billing on 837I Claims
1084	Common Edits and Enhancements Module (CEM) and Receipt, Control, and Balancing Updates – October 2012
1085	Establish an Automated Process between ViPS Medicare System (VMS) and the Provider Enrollment Chain and Ownership System (PECOS) to Post Payment Suspension Alert Codes and Related Data to All Four Durable Medical Equipment Medicare Administrator Contractors (DME MAC) Jurisdictions
1086	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1087	Expand Place of Service Address to Include Full Address
1088	Reporting of Recoupment for Overpayment on the Remittance Advice (RA) with Patient Control Number
1089	Implement Fraud Prevention Predictive Modeling Prepayment Edits
1090	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1091	Enhancements to the Recovery Audit Mass Adjustment/Reporting Process in the Fiscal Intermediary Shared System (FISS)
1092	Affordable Care Act (ACA) Model 1 Bundled Payments for Care Improvement Initiative--Implementation of New Fields for Inpatient Provider Specific File (PSF) and Demonstration Codes
1093	Automated Tracking and Reporting of Recovery Audit-Associated Reopenings and Appeals
1094	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1095	Enhancements to the Recovery Audit Mass Adjustment/Reporting Process in the ViPS Medicare System (VMS)
1096	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
1097	Change in Creation Date for CMS Standard Edit/Audit/Reason Code Reports

Addendum II: Regulation Documents Published in the Federal Register (April through June 2012)

Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and

page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at <http://www.gpoaccess.gov/fr/index.html>. The following Website <http://www.archives.gov/federal-register/> provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our Website at: <http://www.cms.gov/quarterlyproviderupdates/downloads/Regs-2Q12QPU.pdf>
For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters. The rulings can be accessed at <http://www.cms.gov/Rulings/CMSR/list.asp#TopOfPage>. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (April through June 2012)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on

completed decisions as well as pending decisions has also been posted on the CMS Website. For the purposes of this quarterly notice, we list only the specific updates that have occurred in the 3-month period. This information is available on our Website at: www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle (410-786-7491).

Title	NCDM Section	Transmittal Number	Issue Date	Effective Date
Assigned Codes for Home Oxygen Use for Cluster Headache (CH) in a Clinical Trial (ICD-10)	NCD 240.2 CPM 20.30.6	R2465CP	05/17/2012	10/01/2012
Extracorporeal Photophoresis	110.4	R143NCD R2473CP	05/18/2012	10/01/2012
Coding Changes to Ultrasound Diagnostic for Transesophageal Doppler Monitoring	220.5	R2472CP	05/18/2012	10/01/2012

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (April through June 2012)

Addendum V includes listings of the FDA-approved investigational device exemption (IDE) numbers that the FDA assigns. The listings are organized according to the categories to which the devices are assigned (that is, Category A or Category B), and identified by the IDE number. For the purposes of this quarterly notice, we list only the specific updates to the Category B IDEs as of the ending date of the period covered by this notice and a contact person for questions or additional information. For questions or additional information, contact John Manlove (410-786-6877).

Under the Food, Drug, and Cosmetic Act (21 U.S.C. 360c) devices fall into one of three classes. To assist CMS under this categorization process, the FDA assigns one of two categories to each FDA-approved investigational device exemption (IDE). Category A refers to experimental IDEs, and Category B refers to non-experimental IDEs. To obtain more information about the classes or categories, please refer to the notice published in the April 21, 1997 **Federal Register** (62 FR 19328).

IDE	Device	Start Date
BB15045	Magnetic-Activated Cell Sorter (CliniMACS, Miltenyi)	04/12/12
BB15047	Magnetic-Activated Cell Sorter (CliniMACS, Miltenyi)	04/13/12
G100108	Exablate Model 2100 Type 3.0	04/11/12
G100297	HeartAssist 5 VAD System	04/26/12
G110021	Optimesh 1500	06/15/12

G110098	Bondease Topical Skin Adhesive	04/24/12
G110163	The Twin Star Medical ECS Monitoring System	04/05/12
G110187	Cardiac Ablation System	05/16/12
G110200	IN.PACT Admiral Paclitaxel-Eluting Percutaneous Transluminal Angioplasty Balloon Catheter	04/13/12
G110219	1.20 MM Emerge PTCA Dilation Catheter	04/26/12
G110225	Radiesse Dermal Filler	06/15/12
G110231	Circular Mapping Catheters	05/09/12
G110243	Ischemic Global Hypoxia Trial	04/09/12
G120041	Intractable Mesial Temporal Lobe	06/06/12
G120045	Aspireassist Aspiration Therapy System	05/16/12
G120050	Helix Stent System-Helix Clinical Trial	05/17/12
G120055	AVN Video Laryngoscope	05/25/12
G120059	Renal Sympathetic Denervation	04/06/12
G120062	Zeltiq System	06/06/12
G120064	Alphacore	04/12/12
G120066	Cancer Type ID	04/12/12
G120067	Medtronic Phased RF System	04/18/12
G120068	Zeltiq Cooltxt System	06/20/12
G120070	Synvisc-One (Hylan G-F 20)	04/13/12
G120071	Mostegra Trail	04/19/12
G120072	SmartPatch	04/25/12
G120078	St Judes Stimulation System	04/27/12
G120082	Blazer Open-Irrigated Ablation Catheter and Cable Blazer Open-irrigated Ablation Catheter	05/01/12
G120083	Obalon Gastric Balloon System	05/02/12
G120085	Zenith TX2 Low Profile Endovascular Graft	05/02/12
G120086	MOE Medical Device	05/03/12
G120094	BioDesign ESIS Fistula Plug	05/10/12
G120095	Implantable Deep Brain Stimulation System	05/10/12
G120096	Neural Prosthetic System	05/11/12
G120099	Nucleus 24 Multichannel Auditory Brainstem Implant	05/16/12
G120107	Embozene Device	05/30/12
G120108	Pericardial Aortic Bioprosthesis Device	05/30/12
G120109	VYSIS CLL CDX Fish Kit(List Number: 07N67-020) Companion Diagnostic to Merck Compound DINACICLIB	05/29/12
G120116	Cabochon System	06/06/12
G120118	Cochlear Nucleus C1422 Cochlear Implant	06/07/12
G120123	Synergy Everolimus-Eluting Platinum Chromium Coronary Stent System	06/15/12
G120125	Exilis System	06/21/12
G120128	Prevena Incision Management System	06/22/12
G120130	Strattice Reconstructive Tissue Matrix Device	06/28/12

Addendum VI: Approval Numbers for Collections of Information (April through June 2012)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact Mitch Bryman (410-786-5258).

Addendum VII: Medicare-Approved Carotid Stent Facilities, (April through June 2012)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available on our Website at: <http://www.cms.gov/MedicareApprovedFacilities/CASF/list.asp#TopOfPage>. For questions or additional information, contact Sarah J. McClain (410-786-2294).

Facility	Provider Number	Effective Date	State
The following facilities are new listings for this quarter.			
Physicians Regional Healthcare System 8300 Collier Boulevard Naples, FL 34114	1215003348	04/12/2012	FL
Maui Memorial Medical Center 221 Mahalani Street Wailuku, HI 96793	120002	04/12/2012	HI
Franciscan St. Anthony Health – Michigan City 301 West Homer Street Michigan City, IN 46360	150015	04/30/2012	IN
Florida Hospital Heartland Medical Center 4200 Sun 'n Lake Boulevard Sebring, FL 33872	100109	04/30/2012	FL
Aurora Medical Center Grafton 975 Port Washington Road Grafton, WI 53024	520207	05/09/2012	WI
Medical Center of Arlington 3301 Matlock Road Arlington, TX 76015	450675	05/09/2012	TX

Facility	Provider Number	Effective Date	State
Hurley Medical Center 1 Hurley Plaza Flint, MI 48503	230132	05/15/2012	MI
UHS / University of Tennessee Medical Center 1520 Cherokee Trail Suite 200 Knoxville, TN 37920	440015	05/15/2012	TN
Methodist Charlton Medical Center 3500 West Wheatland Road Dallas, TX 75237	1275592131	05/31/2012	TX
Lakeway Regional Medical Center, LLC 100 Medical Parkway Lakeway, TX 78734	1831471291	06/13/2012	TX
Huron Medical Center 1100 S. Van Dyke Bad Axe, MI 48413	230118	06/18/2012	MI
University Physicians Hospital (The University of Arizona Medical Center) 2800 East Ajo Way Tucson, AZ 85713	030111	06/21/2012	AZ
Editorial changes (shown in bold) were made to the facilities listed below.			
AHMC Anaheim Regional Medical Center 1111 West La Palma Avenue Anaheim, CA 92801-2881	050226A	02/08/2006	CA
Methodist Texus Hospital 6700 IH 10 West San Antonio, TX 78201	450388	05/26/2005	TX
Galichia Heart Hospital 2610 N. Woodlawn Wichita, KS 67220-2729	170202	05/16/2005	KS
The following facility has been removed from the listings of Medicare-approved carotid stent facilities.			
Potomac Hospital 2300 Opitz Boulevard Woodbridge, VA 22191	490113	02/02/2006	VA

Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (April through June 2012)

Addendum VIII includes a list of the American College of Cardiology's National Cardiovascular Data Registry Sites. We cover implantable cardioverter defibrillators (ICDs) for certain clinical indications, as long as information about the procedures is reported to a central registry. Detailed descriptions of the covered indications are available in the NCD. In January 2005, CMS established the ICD Abstraction Tool through the Quality Network Exchange (QNet) as a temporary data collection mechanism. On October 27, 2005, CMS announced that the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) ICD Registry satisfies the data reporting requirements in the NCD. Hospitals needed to transition to the ACC-NCDR ICD Registry by April 2006.

Effective January 27, 2005, to obtain reimbursement, Medicare NCD policy requires that providers implanting ICDs for primary prevention clinical indications (that is, patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. Details of the clinical indications that are covered by Medicare and their respective data reporting requirements are available in the Medicare NCD Manual, which is on the CMS Website at <http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961>

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the FDA or in the ACC-NCDR ICD registry. Therefore, for a beneficiary to receive a Medicare-covered ICD implantation for primary prevention, the beneficiary must receive the scan in a facility that participates in the ACC-NCDR ICD registry. The entire list of facilities that participate in the ACC-NCDR ICD registry can be found at www.ncdr.com/webncdr/common

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred to the list of Medicare-approved ICD facilities in the 3-month period. This information is available by accessing our Website and clicking on the link for the American College of Cardiology's National Cardiovascular Data Registry at: www.ncdr.com/webncdr/common. For questions or additional information, contact Joanna Baldwin, MS (410-786-7205).

Facility Name	Address 1	City	State	Zip Code
The following facilities are new listings for this quarter.				
Orange Park Medical Center	2001 Kingsley Avenue	Orange Park	FL	32073
Garfield Medical Center	525 N. Garfield Avenue	Monterey Park	CA	91754
Sutter Solano Medical Center	300 Hospital Drive	Vallejo	CA	94589
Fallbrook Hospital	624 E. Elder Street	Fallbrook	CA	92028
Butler Memorial Hospital	One Hospital Way	Butler	PA	16001
University Medical Center Brackenridge	601 East 15 th Street	Austin	TX	78745
Watauga Medical Center	336 Deerfield Road	Boone	NC	28607
Gulf Coast Surgery Center	411 Second Street East None	Bradenton	FL	32408
Homestead Hospital	975 Baptist Way	Homestead	FL	33030
Frisbie Memorial	11 Whitehall Road	Rochester	NH	03867

Hospital				
University of Texas MD Anderson Cancer Center	1515 Holcombe Boulevard	Houston	TX	77030
Twin Rivers Regional Medical Center	PO Box 728 (only current address)	Kennett	MO	63857
Oconomowoc Memorial Hospital	791 E. Summit Avenue	Oconomowoc	WI	53066
CHRISTUS Santa Rosa Hospital - Westover Hills	11212 Texas 151	San Antonio	TX	78251
Valley Baptist Medical Center-Brownsville	1040 West Jefferson Street	Brownsville	TX	78520
St. Luke's Hospital	1 Shircliff Way	Jacksonville	FL	32204
Georgetown Health Group(Georgetown Memorial Hospital	PO Box 421718 606 Black River Road	Georgetown	SC	29442
Baylor Medical Center at McKinney	5252 W. University Drive	McKinney	TX	75071
The following facilities are no longer participants as of this notice.				
East Cooper Memorial Hospital	2000 Hospital Drive	Charleston	SC	29464
Heart Hospital of New Mexico	504 Elm Street	Albuquerque	NM	87102
Saint Josephs Regional Medical Center	5215 Holy Cross Parkway	Mishawaka	IN	46545
Spring Valley Hospital	5400 South Rainbow Boulevard	Las Vegas	NV	89118
St. Elizabeth Hospital	2233 W. Division	Chicago	IL	60622

Addendum IX: Active CMS Coverage-Related Guidance Documents (April through June 2012)

There were no CMS coverage-related guidance documents published in the April through June 2012 quarter. To obtain full-text copies of these documents, visit the CMS Coverage Website at http://www.cms.gov/mcd/index_list.asp?list_type=mcd_1 and click on the archives link. For questions or additional information, contact Lori Ashby (410-786-6322).

Addendum X: List of Special One-Time Notices Regarding National Coverage Provisions (April through June 2012)

There were no special one-time notices regarding national coverage provisions published in the April through June 2012 quarter. This information is available at www.cms.hhs.gov/coverage. For questions or additional information, contact Lori Ashby (410-786-6322).

**Addendum XI: National Oncologic PET Registry (NOPR)
(April through June 2012)**

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry.

For the purposes of this notice, we are providing only the specific updates that occurred in this 3-month period.

This information is available at

<http://www.cms.gov/MedicareApprovedFacilities/NOPR/list.asp#TopOfPage>.

For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564)

Editorial changes (shown in bold) were made to the facilities listed below.				
Genesis Healthcare Partners-Genesis Imaging Capital Oncology PLLC New name: MultiCare Health System effective – Auburn	121 North Division Street	Auburn	WA	98001
Old name: The West Clinic New name: Methodist West Hospital PET Imaging Center	100 N. Humphreys Boulevard	Memphis	TN	38120
Old name: HACKENSACK MEDICAL AND MOLECULAR IMAGING New name: AMERICAN IMAGING	155 State Street	Hackensack	NJ	07601

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (April through June 2012)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates that have occurred to the list of Medicare-approved facilities that meet our standards in the 3-month period. This information is available on our Website at

<http://www.cms.gov/MedicareApprovedFacilities/VAD/list.asp#TopOfPage>.

For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Facility	Provider Number	Date Approved	State
The following facilities are new listings for this quarter.			
Vanderbilt University Hospital and the Vanderbilt Clinic 1211 21st Avenue South Nashville, TN 37232	440039	04/21/2012	TN
The University of Toledo Medical Center 3000 Arlington Avenue Toledo, OH 43614	360048	04/20/2012	OH
Edward Health Services Corporation 801 South Washington Street Naperville, IL 60540	140231	06/22/2012	IL

**Addendum XIII: Lung Volume Reduction Surgery (LVRS)
(April through June 2012)**

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema

Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. There were no additions to the listing of facilities for lung volume reduction surgery published in the April through June 2012 quarter. This information is available on our Website at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (April through June 2012)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

For the purposes of this quarterly notice, we list only the specific updates to Medicare-approved facilities that meet CMS's minimum facility standards for bariatric surgery and have been certified by ACS and/or ASMBS in the 3-month period. This information is available on our

Website at

www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Kate Tillman, RN, MAS (410-786-9252).

Facility	Provider Number	Date Approved	State
The following facilities are new listings for this quarter.			
Scott and White Memorial Hospital 2401 S. 31st Street Temple, TX 76508	440054	10/25/2010	TX
Kaiser Permanente Hospital Fremont 39400 Paseo Padre Parkway Fremont, CA 94538	1801960513	04/02/2012	CA
Vanderbilt University Medical Center 1215 21st Avenue South Nashville, TN 37232	1396882205	05/07/2012	IL
Editorial changes (shown in bold) were made to the facilities listed below.			
Hillcrest Hospital 729 South East Main Street Simpsonville, SC 29681	42-0037	10/10/2007	SC
St. Luke's Hospital 4201 Belfort Road Jacksonville, FL 32216	100307	04/14/2011	FL
Theda Clark Medical Center 200 Theda Clark Medical Plaza, Suite 410 Neenah, WI 54956	000071445	10/21/2005	WI
Tampa General Hospital 1 Tampa General Circle Tampa, FL 33606	100128	03/03/2006	FL
The following facilities are no longer participants as of this notice.			
UCLA Medical Center 10833 Le Conte Avenue, CHS 72-236 Los Angeles, CA 90095	050262	01/08/2008	CA
Henry Ford Macomb Hospital 13355 East 10 Mile Road Warren, MI 48089	230047	10/07/2008	MI
Anniston Stringfellow Hospital 301 East 18th Street Anniston, AL 36207	01-0038	03/11/2008	AL
Saint Alphonsus Regional Medical Center 1055 North Curtis Road Boise, ID 83706	130007	10/07/2008	ID
South Hampton Community Hospital 2929 South Hampton Road Dallas, TX 75224	670002	08/09/2010	TX
Methodist Hospitals, Inc. 8701 Broadway Merrillville, IN 46410	150002	10/30/2007	IN

Eastern Idaho Regional Medical Center 3100 Channing Way Idaho Falls, ID 83404	13-0018	12/10/2007	ID
Rhode Island Hospital 593 Eddy Street Providence, RI 02903	410007	02/25/2008	RI
Bothwell Regional Health Center 601 East 14th Street Sedalia, MO 65301	260009	05/17/2006	MO

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (April through June 2012)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the April through June 2012 quarter.

This information is available on our Website at www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage. For questions or additional information, contact Stuart Caplan, RN, MAS (410-786-8564).

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